

## REMARKS

Claims 1-7, 9-12, 15, 18, 20, 21, 23, 28 and 33 remain in the application. Claim 1 is the only independent claim. Claims 1-3, 5, 7, 11, 15, 18, 21, 23 and 28 are amended herein. No new matter is introduced.

### **Claim Objections**

The Examiner objected to Claim 5 because of an excess indefinite article “a” in line 2.

By the above amendment to Claim 5, this excess indefinite article is removed. Applicants respectfully request that the Examiner withdraw this objection in light of the above amendment.

In addition, Applicants hereby amend Claims 2, 3, 21, 23 and 28 to correct informalities so that there is an antecedent basis for each use of the definite article “the” in the amended claims.

### **Rejection under 35 U.S.C. §112, second paragraph**

The Examiner rejected Claim 10 under 35 U.S.C. §112, second paragraph for use of a trademark term.

By the above amendment to Claim 11, (the tenth remaining claim in the application and the only claim using a trademark term) the trademark term Velcro™ is removed and replaced by its well known components: fabric comprising multiple small loops and complementary fabric comprising multiple small hooks (in context suitable for Claim 11). Applicants respectfully request that the Examiner withdraw this rejection of Claim 10 or Claim 11 in light of the above amendment.

### **Rejection under 35 U.S.C. §102(a)**

The Examiner rejected Claims 1-7, 12, 20, 21 and 33 under 35 U.S.C. §102, as being anticipated by John Michael’s Corner [online] retrieved from <http://www.oandp.com/news/jmccorner/2000-2008/8.asp> (hereinafter *Michael*).

Applicants claims are directed to a lower leg orthosis that prevents both foot drop and knee hyper-extension. For example, as amended, Claim 1 recites

the foot plate portion and an axis of the spiral-shaped lower leg portion are disposed at an acute angle with respect to one another and wherein a difference between the angle and 90 degrees is greater than about 2 degrees to inhibit hyperextension of the wearer’s knee

The support for this limitation is found in Applicants original paragraph [0049] and in the difference between 90 degrees (item 68 in Applicants' FIG. 5) and the axis (item 56 in Applicants' FIG. 5) of the spiral-shaped lower leg portion, which is at a posting angle (labeled in Applicant's FIG. 5) from the plane of the foot plate. In some contexts, the posting angle is measured by the deviation from 90 degrees (e.g., item 60 in Applicants' FIG. 6, and "orthosis posting angle 60; that is, the angle or degree of inclination from the vertical," Applicants specification paragraph [0044]). Paragraph [0049] of Applicants specification states "The orthosis posting angle . . . is the angle created between the longitudinal axis of the foot plate portion 12 and the longitudinal axis of the lower leg portion 14 of orthosis 10. In some embodiments, the posting angle [deviation] 60 is between 10 degrees and 15 degrees, which eliminates knee hyper-extension for a large number of wearers. For some wearers the preferred posting angle [deviation] 60 may be 20° to 25 ° and for others a posting angle [deviation] 60 of only 0-5° would be preferred to optimize control of [both] the ankle/foot and knee joints. An inadequate posting angle [deviation] 60 can result in . . . inadequate level of control of the knee." (Emphasis added.)

*Michael* is directed to a spiral-shaped lower leg orthosis that is effective at preventing foot drop and easy to put on and take off. Applicants respectfully submit that nothing in *Michael* mentions or suggests preventing knee hyper-extension or a posting angle that deviates from 90 degrees.

The Examiner states that "Michael discloses . . . foot plate portion and the lower leg portion are disposed at an angle with respect to one another (refer to figure above)" (Office Action, page 8, with reference to Claims 15 and 18). However, the only angles shown in the figure to which the Examiner refers are angles of an ascending portion of an outer surface of the lower leg portion, such as at the foot plate. No deviation from 90 degrees is discernable between the foot plate and an axis of the lower leg portion. Indeed, the axis of the spiral-shaped lower leg portion is not indicated in the figure and appears to be at 90 degrees from the foot plate, as in prior art orthoses. It appears that the Examiner has mistaken the angle intended in Claims 15 and 18 for the ascending angle of the spiral outer surface, e.g., from the foot plate. To clarify the distinction, Claim 1 explicitly recites the "axis of the spiral-shaped lower leg portion," (emphasis provided).

There is no reason given in *Michael* to modify the orthosis of *Michael* to introduce such a posting angle that deviates from 90 degrees. All comments about the orthosis in *Michael* are

complimentary; and no problem with knee hyper-extension is noted in *Michael* or any of the references cited by the Examiner. Only Applicants' specification states that it is desirable to control both foot drop and knee hyper-extension in the same orthosis.

Applicants respectfully submit that Claim 1, as amended, is neither anticipated nor rendered obvious by *Michael*. Applicants earnestly request the Examiner to withdraw the rejection of Claim 1 in light of the above amendment.

Claim 7 is amended herein to make clear that the angle described in Claim 7 is an angle the ascending outer surface of the lower leg portion makes, e.g., at the foot plate, and not the posting angle of Claim 1. Therefore Claim 7 is amended to recite "an ascension angle." This is not new matter and is supported in Applicants' specification. For example, Applicants state "The angle or degree of ascension of the spiraling lower leg portion 14 can gradually decrease as the lower leg portion 14 nears the calf section 52," (Applicants specification, paragraph [0037]). This is clearly directed to the outer or inner surface of the lower leg portion, and not to the axis of the spiral shape.

Rejected Claims 2-7, 12, 20, 21 and 33 are dependent claims, each of which depends (directly or indirectly) on Claim 1. Each of Claims 2-7, 12, 20, 21 and 33 is therefore allowable for the reasons given above for Claim 1. In addition, each of Claims 2-7, 12, 20, 21 and 33 introduces one or more additional limitations that independently render it patentable. However, due to the fundamental differences already identified, to expedite the positive resolution of this case a separate discussion of those limitations is not included at this time.

Applicants earnestly request the Examiner to withdraw the rejections of Claims 1-7, 12, 20, 21 and 33 in light of the above amendments.

### **Rejection under 35 U.S.C. §103**

The Examiner rejected Claims 9-11 under 35 U.S.C. §103, as being unpatentable over *Michael* in view of *Ingimundarson et al.*, US Patent Application Publication 2005/0234378 (hereinafter *Ingimundarson*).

As stated above *Michael* does not suggest a posting angle that deviates from 90 degrees, or that such a deviation is useful to prevent or inhibit hyper-extension of the knee.

The Examiner cites *Ingimundarson* for teaching a removable lining in an orthosis.

Applicants respectfully submit that *Ingimundarson* does not cure the deficiencies in *Michael*.

The Examiner does not show where *Ingimundarson* teaches a posting angle that deviates from 90

degrees and therefore does not show in the combination all the limitations of Claim 1, as amended.

Because the combination of *Michael* and *Ingimundarson* does not teach or suggest all the elements of Applicants' Claim 1, the Examiner has not made a *prima facie* case of obviousness and a rejection of Claim 1 under 35 U.S.C. §103 would be improper.

Rejected Claims 9-11 are dependent claims, each of which depends (directly or indirectly) on Claim 1. Each of Claims 9-11 is therefore allowable for the reasons given above for Claim 1. In addition, each of Claims 9-11 introduces one or more additional limitations that independently render it patentable. However, due to the fundamental differences already identified, to expedite the positive resolution of this case a separate discussion of those limitations is not included at this time.

Applicants earnestly request the Examiner to withdraw the rejections of Claims 9-11 in light of the above amendment to Claim 1.

The Examiner rejected Claims 15, 18, 23 and 28 under 35 U.S.C. §103, as being unpatentable over Michael.

As described above, there is no reason given in *Michael* to modify the orthosis of *Michael* to introduce a posting angle that deviates from 90 degrees. All comments about the orthosis in *Michael* are complimentary and no problem with knee hyper-extension is noted in *Michael* or any of the references cited by the Examiner. Only Applicants' specification states that it is desirable to control both foot drop and knee hyper-extension in the same orthosis.

The Examiner states that the angle deviations of Claim 15 and Claim 18 are obvious "since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art," (Office Action, page 8). However, as stated above, *Michael* does not suggest a posting angle that deviates from 90 degrees is useful to prevent or inhibit hyper-extension of the knee. Therefore, the Examiner has not shown that a posting angle that deviates from 90 degrees is known to be a "result effective variable." The effectiveness of this variable is only found in Applicants' specification, e.g., in sections quoted above. Thus determining an optimum value of the posting angle is not rendered obvious by *Michael*.

Because *Michael* does not teach or suggest all the elements of Applicants' Claim 1, the Examiner has not made a *prima facie* case of obviousness; and, a rejection of Claim 1 under 35 U.S.C. §103 would be improper.

Rejected Claims 15, 18, 23 and 28 are dependent claims, each of which depends (directly or indirectly) on Claim 1. Each of Claims 15, 18, 23 and 28 is therefore allowable for the reasons given above for Claim 1. In addition, each of Claims 15, 18, 23 and 28 introduces one or more additional limitations that independently render it patentable. However, due to the fundamental differences already identified, to expedite the positive resolution of this case a separate discussion of those limitations is not included at this time.

Claim 15 and Claim 18 are amended herein to remove the language defining the posting angle deviation, because the intent of that language has already been incorporated into Claim 1 by the amendments above.

Applicants earnestly request the Examiner to withdraw the rejections of Claims 15, 18, 23 and 28 in light of the above amendments.

### **Concluding Remarks**

Reconsideration and further examination is respectfully requested.

Applicants have made a diligent effort to place the claims in condition for allowance. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone Eugene Molinelli, Applicants' Attorney at 703-250-3927 so that such issues may be resolved as expeditiously as possible.

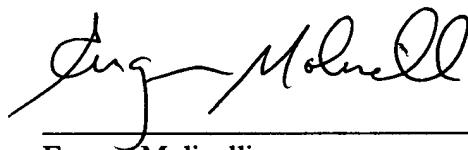
For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

*23 July 2008*

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Date



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